APPENDIX M

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

Amgen Manufacturing, Limited; Immunex Rhode Island Corporation; and Amgen USA Inc.,	**No. 04-CV-12626 MLW**
Plaintiffs,	
vs.	
The Trustees of Columbia University in the City of New York, a New York corporation,	
Defendant.	

PLAINTIFFS' SURREPLY MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

Plaintiffs demonstrated in Opposition to Columbia's Motion to Dismiss their reasonable apprehension of suit by Columbia based upon identical activities to those at issue in the Amgen action. In that action (where Columbia never questioned Amgen's reasonable apprehension), Columbia claimed that Amgen owed it royalties under the '275 patent for sales of EPOGEN® (epoetin alfa) and Enbrel® (etanercept) – the *same* activity that is conducted by Plaintiffs and thus forms the basis for Plaintiffs' apprehension. See Complaint, ¶¶ 6, 11-13, 75(h), and Exhibit D thereto (License Agreement, § 4(b) (referring to covered product). As demonstrated in Plaintiffs' Opposition, their reasonable apprehension based upon those activities is sufficient to support jurisdiction.

In its Reply, Columbia relies principally upon a Federal Circuit decision decided after Plaintiffs filed their opposition, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, ___ F.3d ___, 2005 WL 119890 (Fed. Cir. 2005). Columbia erroneously cites this decision as requiring the reasonable apprehension of an *immediate* lawsuit for jurisdiction in declaratory judgment actions generally.

The Federal Circuit has consistently held that a declaratory judgment plaintiff need not show apprehension of an immediate lawsuit: *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002) (" [A] patentee's present intentions do not control whether a case or controversy exists. The appropriate inquiry asks whether [plaintiff] had a reasonable apprehension that [defendant] would sue it *in the future*.")(internal citations omitted; emphasis added); *Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1484 (Fed. Cir. 1998) (reasonable apprehension is not destroyed by patentee's statement "disavowing" present intent to sue , because Declaratory Judgment Act was intended to forestall "scare-and-run tactics"); *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996) (plaintiff "is not required to wait for the patentee to decide *when* and where to sue") (emphasis added); *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1054 (Fed. Cir. 1995) ("a reasonable apprehension of suit does not require that the patentee be known to be poised on the courthouse steps"); *Goodyear Tire & Rubber Co. v. Releasomers*, 824 F.2d 953, 956 (Fed. Cir. 1987) (the fact that patentee's president had not "at this particular moment authorized a patent infringement action" did not remove apprehension of suit because "a reasonable party could easily infer that [defendant] would *at some time*, bring a patent infringement suit against [plaintiff]"). Indeed, the Federal Circuit has recognized that it would be "unrealistic" to require a declaratory plaintiff to wait until the threat of suit is immediate. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F2d 731, 737 (Fed. Cir. 1988) ("It would obviously be unrealistic to limit the required

apprehension to one of imminent suit against plaintiff when defendant is exhibiting an intent to delay that suit until after defendant's extra judicial enforcement efforts have failed and a trial date more convenient for the defendant has arrived.") With one exception,[1] Columbia fails even to mention any of those cases.

The key sentence on which Columbia relies states that "In order for *this case* to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of *imminent* suit." *Teva*, at *8 (first emphasis added). However, the situation in the *Teva* case, which arose under the Hatch-Waxman Amendments, is very different from the situation at issue here. Pfizer had obtained FDA approval for, and owned two patents ('518 and '699) relating to, the drug sertraline hydrochloride. Teva applied for FDA approval to market a generic version, certifying that the '699 patent was invalid or not infringed. After expiration of a statutory waiting period, Teva sued Pfizer for a declaration to that effect, and Pfizer successfully challenged subject matter jurisdiction. Unlike Plaintiffs here, who are *now* selling products as to which Columbia can later sue them, Teva was not selling allegedly infringing products and would not be for years. When Teva filed its action in January 2003, and entirely apart from the question it raised as to the '699 patent, Teva could not sell the product because the '518 patent (not challenged by Teva) would exclude Teva until it expired in mid-2006, and the Hatch-Waxman Amendments would then entitle another generic company (Ivax) to exclusive generic status until the end of 2006.

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[1] Columbia mentions the *Vanguard* case in a footnote, where Columbia purports to distinguish it by making the inexplicable assertion that "Columbia has not taken any steps to protect the technology covered by the '275 patent." Columbia Reply Memo., p. 10 n. 5. The record in this action, the MDL proceeding and even now in the Patent and Trademark Office impeaches that assertion.

Teva also had much less evidence to support its reasonable apprehension. Pfizer did not assert its '699 patent against Teva,[2] unlike the situation in this case where Columbia sought royalty payments from Amgen and Immunex based upon the '275 patent, and then terminated the License Agreement with Amgen and Immunex covering the '275 patent, an agreement in which Plaintiffs were named as express third party beneficiaries.[3] In addition, the refusal to grant a covenant not to sue by Pfizer, a passive patentee, is very different from Columbia's express exclusion of Plaintiffs from the covenant which was the eventual result of Columbia making affirmative demands and assertions based on the '275 patent.

Additionally, if Columbia were correct that *Teva* established a new and different rule, Columbia's motion should still be denied, because one panel of a circuit may not overturn a rule established by an earlier panel.

> This court has adopted the rule that prior decisions of the panel of the court are binding precedent on subsequent panels unless and until overturned in banc . . . . Where there is direct conflict, the precedential decision is the first.

Newell Cos. Inc. v. Kenney Mfg. Co., 864 F.2d 757, 765 (Fed. Cir. 1988). However, it is highly *unlikely* that the Teva panel majority assumed erroneously that it had the power, or intended, to overturn the many decisions of earlier panels and establish a new general rule that it is the

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[2] Teva cited the fact that Pfizer had listed both patents in the FDA's Orange Book of patents on approved drugs. But that was not an act of aggression because, as the Court noted, Pfizer as the holder of first market approval for the drug was required by statute to list all patents it owned that "'could be reasonably asserted.'" *Id.* at *7, quoting 21 U.S.C. §§ 355(b)(1), (c)(2).

[3] With respect to the Affiliates' Sixth Claim for Relief which Columbia addresses for the first time in reply, Columbia argues that Plaintiffs "have no contractual relationship with Columbia whatsoever." On the contrary, Plaintiffs are express third party beneficiaries of the License Agreement, which runs to "Licensee and its Affiliates" (*see* Compl., Ex. D, §§1(a) and 2(a)). Third party beneficiaries have standing to sue for declaratory relief. *See, e.g., United States v. Southwestern Elec. Coop., Inc.*, 663 F. Supp. 538, 543 (S.D. Ill. 1987).

immediacy of the *patentee's lawsuit* that must be shown rather than the immediacy of the *controversy*.

Such a rule requiring a threat of *immediate* suit by the patentee would completely undermine the purpose of declaratory judgment actions. The Federal Circuit has recognized that "[i]n promulgating the Declaratory Judgment Act, Congress intended to prevent avoidable damages from being incurred by a person uncertain of his rights and threatened with damage by delayed adjudication." *Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673 (Fed. Cir. 1991) (emphasis added). *See also, Goodyear* at 956 ("the purpose of the Declaratory Judgment Act ... in patent cases is to provide the allegedly infringing party relief from uncertainty *and delay* regarding its legal rights") (emphasis added). Thus, *Teva* cannot be read so broadly to preclude a finding of reasonable apprehension merely because the patentee has "delayed adjudication" and there is no threat of "immediate suit."

For the reasons set forth above and in Plaintiffs' Opposition, Columbia's motion to dismiss should be denied.

Dated: February 9, 2005.

Respectfully submitted,

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